

**TABLE C3**  
**Statistical Analysis of Primary Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
<b>Harderian Gland: Adenoma</b>					
Overall rate <sup>a</sup>	1/46 (2%)	0/8 (0%)	0/1 (0%)	0/9 (0%)	5/44 (11%)
Adjusted rate <sup>b</sup>	2.3%	0.0%	0.0%	0.0%	11.7%
Terminal rate <sup>c</sup>	1/40 (3%)	0/1 (0%)	0/0	0/0	5/40 (13%)
First incidence (days)	740 (T)	— <sup>e</sup>	—	—	740 (T)
Poly-3 test <sup>d</sup>	P= 0.0466	P= 0.8706N	P= 0.9995N	P= 0.8645N	P= 0.0994
<b>Harderian Gland: Adenoma or Carcinoma</b>					
Overall rate	1/46 (2%)	1/8 (13%)	0/1 (0%)	0/9 (0%)	5/44 (11%)
Adjusted rate	2.3%	29.7%	0.0%	0.0%	11.7%
Terminal rate	1/40 (3%)	0/1 (0%)	0/0	0/0	5/40 (13%)
First incidence (days)	740 (T)	725	—	—	740 (T)
Poly-3 test	P= 0.0894	P= 0.2609	P= 0.9995N	P= 0.8645N	P= 0.0994
<b>Liver: Hepatocellular Adenoma</b>					
Overall rate	9/47 (19%)	7/47 (15%)	7/48 (15%)	6/48 (13%)	8/48 (17%)
Adjusted rate	20.1%	16.4%	14.8%	14.2%	17.1%
Terminal rate	7/41 (17%)	6/40 (15%)	6/45 (13%)	5/37 (14%)	7/42 (17%)
First incidence (days)	563	667	668	585	738
Poly-3 test	P= 0.4980N	P= 0.4166N	P= 0.3479N	P= 0.3318N	P= 0.4637N
<b>Liver: Hepatocellular Carcinoma</b>					
Overall rate	4/47 (9%)	3/47 (6%)	4/48 (8%)	3/48 (6%)	2/48 (4%)
Adjusted rate	9.0%	7.1%	8.5%	7.2%	4.3%
Terminal rate	3/41 (7%)	2/40 (5%)	4/45 (9%)	3/37 (8%)	1/42 (2%)
First incidence (days)	685	708	740 (T)	740 (T)	691
Poly-3 test	P= 0.2398N	P= 0.5107N	P= 0.6092N	P= 0.5330N	P= 0.3116N
<b>Liver: Hepatocellular Adenoma or Carcinoma</b>					
Overall rate	12/47 (26%)	9/47 (19%)	9/48 (19%)	9/48 (19%)	10/48 (21%)
Adjusted rate	26.8%	21.1%	19.0%	21.3%	21.3%
Terminal rate	10/41 (24%)	7/40 (18%)	8/45 (18%)	8/37 (22%)	8/42 (19%)
First incidence (days)	563	667	668	585	691
Poly-3 test	P= 0.4662N	P= 0.3341N	P= 0.2629N	P= 0.3675N	P= 0.3591N
<b>Lung: Alveolar/Bronchiolar Adenoma</b>					
Overall rate	6/48 (13%)	0/9 (0%)	0/2 (0%)	0/11 (0%)	6/48 (13%)
Adjusted rate	13.5%	0.0%	0.0%	0.0%	12.9%
Terminal rate	5/41 (12%)	0/1 (0%)	0/0	0/0	5/42 (12%)
First incidence (days)	654	—	—	—	738
Poly-3 test	P= 0.5535	P= 0.4831N	P= 0.7506N	P= 0.4687N	P= 0.5848N
<b>Skin: Fibrosarcoma</b>					
Overall rate	5/48 (10%)	1/11 (9%)	5/7 (71%)	4/14 (29%)	5/47 (11%)
Adjusted rate	11.0%	15.8%	71.4%	46.7%	10.8%
Terminal rate	2/41 (5%)	1/4 (25%)	4/6 (67%)	1/3 (33%)	2/41 (5%)
First incidence (days)	447	740 (T)	668	643	638
Poly-3 test	P= 0.2186N	P= 0.6405	P= 0.0001	P= 0.0329	P= 0.6198N

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**Statistical Analysis of Primary Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
<b>Skin (Subcutaneous Tissue): Fibrosarcoma or Sarcoma</b>					
Overall rate	6/48 (13%)	1/11 (9%)	5/7 (71%)	4/14 (29%)	5/47 (11%)
Adjusted rate	13.1%	15.8%	71.4%	46.7%	10.8%
Terminal rate	2/41 (5%)	1/4 (25%)	4/6 (67%)	1/3 (33%)	2/41 (5%)
First incidence (days)	447	740 (T)	668	643	638
Poly-3 test	P= 0.1576N	P= 0.6822	P= 0.0003	P= 0.0526	P= 0.4919N
<b>All Organs: Malignant Lymphoma</b>					
Overall rate	5/48 (10%)	2/48 (4%)	1/48 (2%)	5/48 (10%)	7/48 (15%)
Adjusted rate	11.3%	4.6%	2.1%	11.7%	14.8%
Terminal rate	5/41 (12%)	1/40 (3%)	1/45 (2%)	4/37 (11%)	6/42 (14%)
First incidence (days)	740 (T)	291	740 (T)	282	584
Poly-3 test	P= 0.0400	P= 0.2139N	P= 0.0871N	P= 0.6093	P= 0.4279
<b>All Organs: Benign Neoplasms</b>					
Overall rate	15/48 (31%)	8/48 (17%)	8/48 (17%)	8/48 (17%)	17/48 (35%)
Adjusted rate	33.0%	18.4%	16.9%	19.0%	36.4%
Terminal rate	11/41 (27%)	6/40 (15%)	7/45 (16%)	7/37 (19%)	16/42 (38%)
First incidence (days)	563	440	668	585	738
Poly-3 test	P= 0.0779	P= 0.0813N	P= 0.0583N	P= 0.1045N	P= 0.4518
<b>All Organs: Malignant Neoplasms</b>					
Overall rate	13/48 (27%)	10/48 (21%)	11/48 (23%)	16/48 (33%)	16/48 (33%)
Adjusted rate	28.5%	22.5%	22.9%	35.4%	33.3%
Terminal rate	9/41 (22%)	6/40 (15%)	8/45 (18%)	8/37 (22%)	10/42 (24%)
First incidence (days)	447	291	624	282	584
Poly-3 test	P= 0.0992	P= 0.3220N	P= 0.3529N	P= 0.3164	P= 0.3895
<b>All Organs: Benign or Malignant Neoplasms</b>					
Overall rate	24/48 (50%)	16/48 (33%)	16/48 (33%)	21/48 (44%)	27/48 (56%)
Adjusted rate	52.0%	35.2%	33.3%	46.5%	56.3%
Terminal rate	19/41 (46%)	10/40 (25%)	13/45 (29%)	13/37 (35%)	21/42 (50%)
First incidence (days)	447	291	624	282	584
Poly-3 test	P= 0.0352	P= 0.0672N	P= 0.0514N	P= 0.3765N	P= 0.4172

(T)Terminal sacrifice

<sup>a</sup> Number of neoplasm-bearing animals/number of animals examined microscopically

<sup>b</sup> Poly-3 estimated neoplasm incidence after adjustment for intercurrent mortality

<sup>c</sup> Observed incidence at terminal kill

<sup>d</sup> Beneath the control incidence are the P values associated with the trend test. Beneath the exposed group incidence are the P values corresponding to pairwise comparisons between the controls and that exposed group. For all tissues except the liver, only the pairwise comparisons between the 150 ppm group and control group are unbiased; overall rates and all other pairwise comparisons may not be valid. The Poly-3 test accounts for differential mortality in animals that do not reach terminal sacrifice. A negative trend or a lower incidence in an exposure group is indicated by N.

<sup>e</sup> Not applicable; no neoplasms in animal group